UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

Case No. _____

v.

ZARZAMORA HEALTHCARE LLC, RITE-AWAY PHARMACY & MEDICAL SUPPLY #2 and JITENDRA CHAUDHARY.

Defendants.

_____/

DECLARATION OF AMY WITTE, PHARM. D

I, Amy Witte, declare under penalty of perjury that the following statements are true and correct:

Professional and Academic Experience

1. The opinions expressed in this declaration are based on my more than sixteen years of experience as a pharmacist. I have been licensed to practice pharmacy in Texas since 2004. I completed a residency in Pharmacy Practice at the South Texas Veterans Health Care System in San Antonio, TX in June 2005 and an additional residency in Primary Care Pharmacy at the South Texas Veterans Health Care System in July 2006.

2. I joined the faculty of the University of the Incarnate Word in 2006. I am currently a Professor of Pharmacy Practice where I teach courses on the practice of

pharmacy, including the laws and regulations of practicing pharmacy. I also work as a Primary Care Clinical Pharmacy Specialist at the South Texas Veterans Health Care System. My clinic focuses on providing diabetes, hypertension, and dyslipidemia disease state management as a consult service within the primary care team.

3. In this capacity, I teach students the practical considerations of complying with the federal statutes and regulations pertaining to the practice of pharmacy. Chief among those statutes is the Controlled Substance Act, 21 U.S.C. § 801 et seq. ("CSA"), and the regulations promulgated under the CSA, particularly 21 C.F.R. Part 1300. These matters are central to the practice of pharmacy when dispensing controlled substances. I am familiar with the rules and regulations of the practice of pharmacy in Texas.

4. Based on my training and experience, I am specifically familiar with 21 C.F.R. § 1306.04(a), the federal regulation governing the issuance of controlled substance prescriptions, and 21 C.F.R. § 1306.06, the federal regulation that provides that a "prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a [DEA] registered pharmacy."

5. I received my Doctor of Pharmacy from The University of Texas at Austin College of Pharmacy in 2004. I am a member of the American Society of Health-System Pharmacists, American Pharmacists Association, American Association of Colleges of Pharmacy, Texas Society of Health System Pharmacists, and Central Texas Society of Health System Pharmacists.

Materials Reviewed

6. I was asked by the U.S. Department of Justice to review prescription dispensing records of Rite-Away Pharmacy from August, 2017, to the present, to evaluate whether the pharmacists filling prescriptions for controlled substances at the pharmacy were appropriately exercising their corresponding responsibility to ensure the medical legitimacy of the prescriptions dispensed and dispensing controlled substances in the usual course of professional pharmacy practice.

7. Specifically, I was asked to evaluate whether the pharmacist identified and resolved red flags when dispensing controlled substance prescriptions and to evaluate the attempts, if any, to resolve red flags.

8. The materials that I reviewed included a PDMP report for Rite-Away Pharmacy, individual patient prescriptions, and individual patient profiles. I also reviewed autopsy records for individual M.P.

Practice Standards for Retail Pharmacists

9. The standard of care in the state of Texas requires a pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy. 22 TAC § 295.3. A pharmacist is required to exercise sound professional judgment with respect to any prescription drug order dispensed. *See* 22 TAC § 291.29(a). A pharmacist must make every reasonable effort to ensure that a prescription has been issued for a legitimate medical purpose by a practitioner in the course of medical practice. 22 TAC § 291.29(b). A pharmacist must not dispense a controlled substance if the pharmacist knows or should know that a prescription was issued illegitimately. 22 TAC § 291.29(b).

10. In practical terms, this means that a pharmacist must perform certain steps prior to filling any new or refill-controlled substance prescription. This includes evaluating a prescription drug or medication orders and a patient medication record for: (A) a known allergy; (B) a rational therapy-contraindication; (C) a reasonable dose and route of administration; (D) reasonable directions for use; (E) duplication of therapy; (F) a drug-drug interaction; (G) drug-food interaction; (H) drug-disease interaction; (I) adverse drug reaction; and (J) proper use, including overuse or underuse. TOC 551.033(19). Indeed, "A pharmacist shall make every reasonable effort to prevent inappropriate dispensing due to fraudulent, forged, invalid, or medically inappropriate prescriptions in violation of a pharmacist's corresponding responsibility." 22 TAC § 291.29(f).

11. The standard of care also requires compliance with 21 C.F.R. § 1306.04, which imposes a corresponding responsibility on every pharmacist to ensure that a prescription for a controlled substance was issued for a legitimate medical purpose in the usual course of the prescriber's professional medical practice.

12. Thus, the standard of care for the practice of pharmacy requires that pharmacists recognize certain signs of an illegitimate prescription, drug diversion, or abuse, commonly known as "red flags." The standard of care also requires that a pharmacist consider, evaluate, and resolve any "red flags" before dispensing a prescription drug. The prescriber, the patient, or the prescription may present a red flag.

13. My opinion is based on the procedure every reasonable pharmacist in the state of Texas would follow and is not specific to the standard of care utilized at the VA

South Texas Outpatient Clinic or unique to the curriculum I teach as a professor of pharmacy.

14. To evaluate a prescription, a pharmacist must first, determine the validity of a prescription. A prescription is valid when it is based on valid pre-existing patient-practitioner relationship and when it has been issued for a legitimate medical purpose. The pharmacist would verify that the prescription contains the patient's name and correct current address. The pharmacist would then look at the bottom of the prescription to verify that the prescribing physician has manually signed the prescription and has entered the date of the prescription and a DEA number. Next, the pharmacist would look at the body of the prescription for the drug name, the strength or dose of the drug, the quantity to dispense, and the directions for use. After reviewing the prescription, the final step would be for the pharmacist to review the patient's profile for corresponding notes, length of use and any documentation regarding prescription history.

15. Once the patient's records have been reviewed, and if the pharmacist determines a reason for concern, i.e. a "red flag," in any of the above-mentioned areas, the pharmacist must take the appropriate steps to resolve the area of concern before filling the prescription.

16. Although the prescribing of any controlled substance would bring a heightened concern because of its potential for abuse, some of the red flags of diversion that a reasonable pharmacist practicing in Texas should be familiar with include the following, which are generally described in 22 TAC § 291.29(c) and (f):

a. Prescriptions for controlled substances are for unusually large quantity or

drug strength;

b. Prescriptions by a prescriber presented to the pharmacy are routinely for controlled substances commonly known to be abused drugs, including opioids, benzodiazepines, muscle relaxants, psychostimulants, or any combination of these drugs;

c. Multiple persons with the same address present substantially similar controlled substance prescriptions from the same practitioner;

d. Substantially similar prescriptions for controlled substances, commonly paired with other drugs, for numerous persons, indicating a lack of individual drug therapy in prescriptions issued by the practitioner;

e. The distance a patient travels between to get a prescription from a prescriber or to fill a prescription at a pharmacy;

f. A practitioner may raise a red flag because of the number of prescriptions for controlled substances that practitioner issues which are presented at a pharmacy.

17. When a prescription contains one or more "red flags" concerning a prescription for a controlled substance, a pharmacist must take steps to resolve the "red flag" to determine whether or not the prescription is for a legitimate medical purpose before filling the prescription. The pharmacist should also document the steps taken to resolve a red flag in the pharmacy's records, often either on the prescription itself or in the patient record system. The lack of any documentation indicating that a red flag was resolved means that a "red flag" was not resolved.

18. A pharmacist may take various steps to resolve a red flag depending on the type of red flag presented. These steps involve obtaining more information from the patient or prescriber or both, to ensure that the controlled substances prescribed are for a legitimate medical purpose.

Opinions Regarding Rite-Away Pharmacy

19. The examples described below illustrate obvious red flags which would be known to any pharmacist evaluating the prescriptions presented. These red flags should have been identified and resolved prior to dispensing the controlled substances because they would raise serious and significant concern about the medical legitimacy of the controlled substances being dispensed. Texas law and regulations require pharmacists to conduct a prospective drug utilization review to examine the appropriateness of prescription drug or controlled substance therapy prior to filling a prescription. Competent pharmacists should document in the patient profile any comments regarding a patient's drug therapy. Based on my education, experience and expertise, a number of the prescriptions filled by Rite-Away Pharmacy raised significant "red flags" that the pharmacists did not appear to resolve before providing the drugs to the patients. If the pharmacists had conducted an appropriate drug utilization review, they would have identified the "red flags," and if they appropriately documented a resolution for any "red flag" it should be contained within the records I reviewed. It is my professional opinion that the pharmacist/pharmacists at Rite-Away Pharmacy should not have filled those prescriptions without obtaining information that satisfactorily resolved those "red flags" and without documenting the resolution of those red flags.

Examples of such conduct are as follows:

20. M.P. received prescriptions for a high volume of opioids, fentanyl and benzodiazepines. This is a red flag. Beyond the high volume of dangerous opioids in combination with benzodiazepines, M.P. was receiving prescriptions for these controlled substances from multiple prescribers, which is a red flag. Despite the high volume prescriptions, the patient's pharmacy records did not clearly specify a condition or indication to warrant the use of narcotics, benzodiazepines, or fentanyl patches. The pharmacist dispensing the controlled substances to M.P. knew or should have known that the dosages and combinations posed serious risks to M.P. Based on my years of experience, the pharmacist knew or should have known that these medications were not for a legitimate medical purpose and should not have been filled. Any reasonable pharmacist would recognize these circumstances as an indication that the controlled substance prescriptions presented were not for a legitimate medical purpose. Tragically, the records I reviewed showed that M.P. suffered a fatal fentanyl overdose on September 11, 2017, within nine days of Rite-Away filling her prescription for fentanyl.

21. Patient Y.A. received excessive prescribing of multiple short and long acting narcotics by Dr. A.H. and Dr. S. G. This is a red flag which the pharmacy did not resolve. I could find no indication for use on multiple schedule II prescriptions documented in the pharmacy's records. Patient Y.A. was receiving substantially similar controlled substance prescriptions as many other patients from the same providers, which is also a red flag because it reflects a lack of individualization of therapy. Finally, it appears that this patient was prescription shopping—using different providers for narcotic

prescriptions—which is a red flag. For example, a prescription for Embeda (naltrexone and morphine) was filled for a 30-day supply on September 25, 2017 by Dr. S.G. Also on September 25, 2017, this patient received a 30-day supply of oxycodone from Dr. A.H. Based on the materials I reviewed, the pharmacist knew or should have known that the controlled substance prescription dispensed to Y.A. were not for a legitimate medical purpose and should not have been filled. Any reasonable pharmacist would recognize these circumstances as an indication that the controlled substance prescriptions presented were not for a legitimate medical purpose.

22. T.B. received a high volume of oxycodone and hydrocodone prescriptions, which is a red flag. He was prescribed excessive narcotics by multiple different providers, Dr. A.H., Dr. S.G., and Dr. D.C., which is another red flag, and used different providers each month to obtain opioid prescriptions, which is also a red flag. T.B. was receiving he same strength, quantity, and directions for use of narcotics as his wife, R.B. reflecting a lack of individualization of therapy, yet another red flag. Based on the materials I reviewed, the pharmacist knew or should have known that the controlled substance prescriptions dispensed to T.B. were not for a legitimate medical purpose and should not have been filled. Any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose.

23. R.B. was prescribed a high volume of oxycodone and hydrocodone by several different providers, raising red flags. According to the pharmacy's records, R.B. received the same strength, quantity, and directions for use of narcotics as her husband, T.B., indicating a lack of individualized therapy, which is a red flag. Based on the

materials I reviewed, the pharmacy failed to identify or document a resolution to these red flags. Any reasonable pharmacist would know or recognize these circumstances as an indication that the controlled substance prescriptions presented were not for a legitimate medical purpose.

24. J.C. was prescribed a high volume of oxycodone and OxyContin prescriptions, which is a red flag. J.C. received both brand name and generic versions of oxycodone prescriptions from Dr. A.H. on the same day, which is duplicative therapy and a red flag. The pharmacy's records show that the patient used different providers each month for his narcotic prescriptions. For example, in October 2018, Dr. A.H. supplied the patient with a prescription for 30-day supplies of oxycodone 30 mg and OxyContin 60 mg. In November 2018, Dr. S.G. supplied the same prescriptions to the patient. Dr. A.H. also supplied the patient a Narcan prescription. J.C. received the same strength, quantity, and directions of use for narcotics as his wife N.C., reflecting a lack of individualized therapy, which is a red flag. Based on the materials I reviewed, the pharmacy failed to identify or document a resolution to these red flags. Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose.

25. N.C. was prescribed a high volume of prescriptions for oxycodone, OxyContin, and fentanyl. She received both brand name and generic oxycodone prescriptions from Dr. A.H. and Dr. S.G. on the same day, raising multiple red flags because of the doses, overlapping therapy, and multiple prescribers. N.C. also had a Narcan prescription prescribed by Dr. A.H. Based on the pharmacy's records, there was

no clinical purpose noted for benzodiazepines prescribed to the patient. It appears that the patient used different providers each month for narcotic prescriptions. For instance, this patient obtained prescriptions for oxycodone, OxyContin, and fentanyl from Dr. A.H. in July 2018. The following month, in August 2018, Dr. S.G. prescribed the patient oxycodone and methadone. It is evident that this patient received a lack of individualization of therapy because she received the same strength, quantity, and directions for use of narcotics as her husband, J.C. Based on the materials I reviewed, the pharmacy failed to identify or document a resolution to these red flags. Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose.

26. C.F. received prescriptions mainly of short and long acting opioid prescriptions except for an occasional vitamin prescription. It is a red flag when a pharmacy customer receives mostly opioid prescriptions. Another red flag is raised here by the high volume of oxycodone and hydrocodone prescribed. C.F.'s opioid prescriptions were prescribed by Dr. A.H., Dr. S.G., and Dr. D.C. When the same prescribers exhibit a pattern of writing substantially similar, high dose prescriptions for opioids, it is a significant red flag. Additionally, there were missing indications for use on some of the schedule II prescriptions provided. Based on the materials I reviewed, the pharmacy failed to identify or document a resolution to these red flags. Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose.

27. L.H. received two short acting opioids, hydrocodone and oxycodone, each

month from Dr. A.H., Dr. S.G., and Dr. D.C. The lack of individualization of therapy for this patient is apparent because she received the same prescription drug strength, quantity, and directions for use as other patients of these providers. An additional red flag is raised when an individual receives two immediate release, or short acting opioids. Based on the materials I reviewed, the pharmacy failed to identify or document a resolution to these red flags. Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose.

28. M.L. patient received hydrocodone and methadone prescriptions each month from Dr. A.H., Dr. S.G., and Dr. D.C., which is a red flag. M.L. was receiving substantially similar controlled substances as her husband, G.L., from the same providers, which is a red flag. Another red flag is raised because M.L. traveled an unusual distance to fill her prescriptions at Rite Away Pharmacy in San Antonio, which is 3.5 hours away from her home. Additionally, M.L. received hydrocodone prescribed to be taken twice daily, which indicates a lack of legitimate medical use because hydrocodone is a short-acting opioid and two doses per day would typically not be sufficient to provide pain relief for a full day's duration. The same red flags were present for M.L.'s husband, G.L. Based on the materials I reviewed, the pharmacy failed to identify or document a resolution to these red flags. Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose.

29. A.M. and J.M. are a husband and wife couple according to the pharmacy's

records. A.M. and J.M. both received opioids, benzodiazepines, and amphetamine every month from Dr. A.H., Dr. S.G., and Dr. D.C., raising several red flags. They each received a prescription for phentermine that was filled monthly from 2017 – 2019, which raises a red flag concerning legitimate medical use because phentermine is generally only approved for short-term uses of no more than six weeks. According to the pharmacy's records, there was no indication for use on the phentermine prescription. Based on the materials I reviewed, the pharmacy failed to identify or document a resolution to these red flags. Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose.

30. C.F. received monthly prescriptions for opioids, benzodiazepines, and amphetamines from different providers, raising several red flags. It is a red flag when a customer receives controlled substances from multiple prescribers. The combination of opioids and benzodiazepines poses significant risks of respiratory depression and overdose. The addition of amphetamines, another schedule II controlled substance prone to abuse, raises another red flag. Moreover, the pharmacy's records do not document any indication for use for the prescriptions. Based on the materials I reviewed, the pharmacy failed to identify or document a resolution to these red flags. Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose.

31. M.R. and S.R. are husband and wife couple according to the pharmacy's records. Both received a high volume of hydrocodone, hydromorphone, morphine, oxycodone, and amphetamine prescriptions from Dr. A.H. and Dr. D.C., raising

significant red flags regarding the combination, doses, and multiple prescribers. Based on the materials I reviewed, the pharmacy failed to identify or document a resolution to these red flags. Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose.

32. B.O. received hydrocodone, oxycodone, morphine and benzodiazepine prescriptions by Dr. A.H., S.G. and D.C., raising significant red flags regarding the combination, doses, and multiple prescribers. The pharmacy's records showed that B.O.'s morphine prescription lacked an indication for use. In addition to the above-described prescriptions, the patient was prescribed Narcan by Dr. A.H. Narcan is an opioid antagonist and is designed to reverse the effects of opioid overdose. Based on the materials I reviewed, the pharmacy failed to identify or document a resolution to these red flags. Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose.

33. L.W. received prescriptions for hydrocodone, oxycodone, and alprazolam from Dr. A.H. and Dr. D.C., raising significant red flags regarding the combination, doses, and multiple prescribers. L.W. was also prescribed Narcan by Dr. A.H. Of those patient prescriptions, there were missing indications on several of the alprazolam prescriptions. Additionally, this patient lacked individual drug therapy as it pertains to prescriptions issued by Dr. A.H. and Dr. D.C. The patient received the same drug, strength, and directions for use as other patients seen by these same doctors. Based on the materials I reviewed, the pharmacy failed to identify or document a resolution to

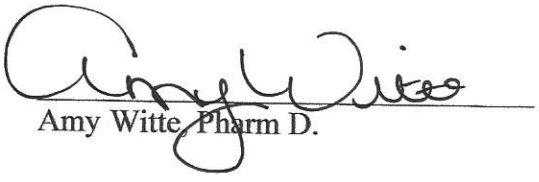
these red flags. Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose.

34. In summary, Rite-Away's dispensing of these prescriptions led to a number of unresolvable red flags. Based on my review, it appears these red flags were not identified or resolved prior to dispensing the prescriptions. Some of the red flags identified during the review include 1) identical prescriptions for the same controlled substances, for numerous persons indicating a lack of individual therapy, in prescriptions issued by the practitioner, 2) prescriptions by a prescriber that are routinely for controlled substances known to be abused drugs, including opioids, benzodiazepines, muscle relaxers, psychostimulants, and/or cough syrups containing codeine , or any combination of these dugs 3) prescriptions for controlled substances by a prescriber that contain non-specific or no diagnoses or lack the intended use of the drug 4) the patient's address is a significant distance from the pharmacy and/or from the prescriber's office and 5) multiple persons with the same address present similar controlled substance prescriptions from the same prescriber (TSBP Rule § 291.29).

35. In my professional opinion, Rite-Away Pharmacy failed to comply with Texas law, specifically TSBP Rule § 291.29, Professional Responsibility of a Pharmacists. The pharmacist/pharmacists at Rite-Away Pharmacy should not have filled

those prescriptions without obtaining information that resolved those "red flags" and without documenting the resolution of those red flags. It was brought to my attention that majority of the red flags were easily detected and seemed to remain unresolved. Both technical/record keeping, and inappropriate clinical violations were noted throughout the prescription review. Most of these prescriptions should have been questioned by the pharmacist/pharmacists prior to dispensing. The red flags presented during the Rite-Away prescription review would have prompted any competent pharmacist to contact the physician to clarify the prescription before processing. It is the pharmacist responsibility to further investigate and determine the legitimacy of the controlled substance prescriptions. Most of the providers also seemed to write for the same medications/directions for all the patients despite their acute or chronic condition(s). Lastly, the frequent use of certain medications such as narcotics, anxiolytics, muscle relaxants and amphetamines along with lack of individualization of therapy for each patient also raised concern for a possible pill mill operation.

Executed on 4-7-21.



Amy Witte, Pharm D.